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08/292,490	08/18/94	BARCLAY	W 2997131
		18N2/1108	WARE, J. EXAMINER
		GARY J. CONNELL 1700 LINCOLN STREET SUITE 3500 DENVER CO 80203	ART UNIT PAPER NUMBER 3
			1808
			DATE MAILED: 11/08/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 08/18/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION
(See back of PTO-948)

1. Claims 14-20

are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 14-20

have been cancelled.

3. Claims _____

are allowed.

4. Claims 14-20

are rejected.

5. Claims _____

are objected to.

6. Claims _____

are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received or been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

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Claims 14-20 are presented for examination.

The Preliminary Amendment filed August 18, 1994 has been received and entered. Further, the cancellation of claims 1-13 and 21-37 is acknowledged.

The drawings are objected to because of the reasons set forth on the enclosed PTO-948. Correction is required.

Applicant is required to submit a proposed drawing correction in response to this Office action. However, correction of the noted defect can be deferred until the application is allowed by the examiner.

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to set forth an enabling disclosure.

The specification fails to properly set forth clear enablement for optimal results obtained for use of small aggregates containing mixtures of the algae types:

Thraustochytrium and *Schizochytrium*. It is unclear that the aggregates are made up of both types or that such aggregates are comprised of only one type since the examples teach that optimal results are obtained for *Thraustochytrium* and not for

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Schizochytrium. Also it appears that the cellular aggregates are prepared from either algae cells of the genus *Thraustochytrium* or *Schizochytrium* and not both. It is unclear that applicants have properly enabled for mixtures of the two genera and/or compared results with those prepared from an independent genus.

Claims 14-20 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 14-20 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a non-chloride containing sodium salt media used to produce the claimed microfloral biomass, and particularly sodium sulfate, and the specific set of culturing conditions utilized as exemplified in the instant specification since the claimed *Thraustochytrium* and *Schizochytrium* cultured in such media are taught to form much smaller clumps (i.e. aggregates) than those cultured in high chloride media (see instant specification, page 3, lines 16-21). Further, the specification is only enabling for the specific strains of *Thraustochytrium* and *Schizochytrium*.

There would be an undue burden of experimentation placed upon one of ordinary skill in the art in order to produce the claimed microfloral biomass having the claimed cell aggregate sizes without using the specific set of culturing conditions employed as well as the specific non-chloride salts used. This point is especially pertinent since the specification appears to

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only compare the claimed improved cell clumping effect using the non-chloride salt, sodium sulfate, at specific concentrations for *Thraustochytrium*. No other non-chloride salts are demonstrated in the specification to show the claimed clumping effect. Thus, it would be difficult for one of ordinary skill in the art to assume that any non-chloride salt at any concentration would work without extensive testing. Moreover, the burden of testing all species and strains of the two genera claimed would be overwhelming to one of ordinary skill, since well defined optimization parameters have not been clearly set forth in the claims. In addition it would be difficult to determine which strains are oleaginous species, having the ability to accumulate the specific claimed lipid concentrations in the claimed microfloral biomasses. Therefore, the claims are too broad to be supported by the enabling disclosure.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 14-20 are rejected under 35 U.S.C. § 101 because the claimed invention appears to be drawn to non-statutory subject matter.

The instant claims appear to be directed to an organism which has not been purified from nature. Organisms which have not been purified from nature, or designated as being

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"biologically pure", constitute natural living things and are thus, rendered non-statutory and not patentable subject matter. It is suggested that applicants include language in which to distinguish the claimed invention from non-statutory subject matter. Thus, it is suggested to include the language "biologically pure" in order to distinguish said subject matter.

Claims 14-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 19 and 20 are rendered vague and indefinite for the recitation of "less than about" since such language appears to be conflicting in that "about" means that the size can be a little less than 150 microns or a little more than 150 microns. Therefore, "about" is confusing when used with "less than" which means just what it states less not more. Further, it is suggested to amend the language "a cell aggregate size less than about" to include --in diameter-- which could be inserted after the term "microns" in order to be consistent with the description of the claimed cell aggregates on page 3, lines 20-25 of the instant specification.

Claim 16 is rendered vague and indefinite for the recitation of "and" on lines 4-5 of the claim. It appears that applicants have failed to add or delete claim language in order to set forth "mutant strains derived therefrom". Furthermore the language "an

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"organism" is rendered vague and indefinite in that it is unclear if "an organism" is of a biologically pure microorganism selected from the claimed Markush Group; and it is suggested to delete "an organism" and replace it with --a biologically pure microorganism--. Also the language "and mutants thereof" is rendered vague since it is unclear that these claimed mutants would be derived from mutant strains therefrom. Thus, it is suggested that applicants delete the language "and mutants thereof" and insert in its place --and mutant strains derived therefrom--. In addition the language "wherein said mutants" should be replaced with the following language: --wherein said *Thraustochytrium*, *Schizochytrium*, and mixtures thereof--.

Claim 18 is rendered vague and indefinite in that it lacks antecedent basis for the recitation of "wherein *Thraustochytrium* and *Schizochytrium*"; and it is suggested that applicants insert --said-- before the term "wherein" of the above phrase. In addition it appears that "and mixtures thereof" have been omitted and for consistency it is suggested to insert --*Thraustochytrium*, *Schizochytrium*, and mixtures thereof-- and delete "*Thraustochytrium* and *Schizochytrium*" in order to clarify that "and mixtures thereof" would also have at least about 15% of the total sterol content.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section

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102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 14-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Kendrick et al. in view of Bajpal et al., and if necessary in further view of World Patent 89/00606.

The claims are drawn to a microfloral biomass comprising *Thraustochytrium*, *Schizochytrium* and mixtures thereof. Further, these algae types and mixtures thereof have a cell aggregate size less than about 150 microns. In addition these algae and mixtures thereof can optionally be grown in a culture medium containing sodium sulfate, and are capable of producing omega-3 high unsaturated fatty acids.

Kendrick et al. teach the marine fungi *Thraustochytrium* and *Schizochytrium* which are capable of producing high unsaturated fatty acids. In addition these fungi are taught to be grown in the same culture medium containing magnesium sulfate, copper sulfate, sodium phosphate, etc. (see col. 1, lines 30-45). Upon culturing of these microorganisms the reference teaches that certain fungi, which are referred to as oleaginous species, have

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the ability to accumulate up to 85% lipid as a storage compound in the biomass. This accumulation is further taught to be triggered by exhaustion of a growth nutrient, other than a carbon source (see col. 1, lines 37-42).

Bajpal et al. teach optimization of production of docosahexaenoic acid (DHA) by *Thraustochytrium aureum* A.T.C.C. 34304. A specific culture medium is taught to contain sodium carbonate, ammonium sulfate/sulfite, etc. (see the abstract and the Materials and Methods section). Furthermore, *Thraustochytrium aureum* is taught to produce significant quantities of DHA and has in addition been found to display light-stimulated growth (page 509, col. 2, lines 1-14).

The World Patent teaches the use of microbes such as those selected from the genera *Thraustochytrium* and *Schizochytrium* in which to produce omega-3-fatty acids (see abstract and page 5, lines 20-25). Further, these microorganisms are grown heterotrophically and harvesting is carried out by centrifugation or freeze drying (see page 6, lines 10-25).

The claimed subject matter differs from the disclosure of Kendrick et al. (hereinafter called Kendrick) in that a specific cell aggregate size less than about 150 microns as claimed herein is not specifically disclosed. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to combine the teachings of Bajpal et al. (hereinafter called Bajpal) with those of Kendrick in order to optimize light

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conditions for the claimed algal cultures and thus, produce a microfloral biomass having a cell aggregate size less than 150 microns, as claimed herein.

Clearly a biomass having small cellular aggregates (i.e. less than 150 microns) would have been more optimal for lipid production. This form of reasoning stems from Bajpal, wherein this reference teaches a maximum yield of DHA can be produced in light-exposed cultures of the claimed genera (i.e. *Thraustochytrium*). Thus, one of ordinary skill in the art would have been motivated to provide small size cellular aggregates since those cells would have been more susceptible to light penetration. One of skill would have known that an increase or enhanced production of DHA would have been obtained using small aggregates of less than 150 microns or less than 50 microns since the surface area for light exposed cultures would be increased.

Furthermore, a microfloral biomass comprising two algal types such as those claimed herein would have been expected to provide an omega-3 high unsaturated fatty acid content of at least about 0.5% dry weight as the World Patent clearly teaches these microorganisms to be grown heterotrophically, harvested (i.e. biomass), and extracted therefrom for lipid products (see abstract and page 5, lines 20-30). More specifically, the samples harvested in the World Patent produce lipid fractions that constitute as much as 10 to 50 % of the total fatty acid fraction (see page 8, lines 5-10).

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Clearly one of skill would have been motivated to formulate a biomass of the claimed genera having a small aggregate size as claimed herein. The use of sodium sulfate as claimed in claim 15 would have been an optimal choice of functional equivalents for non-chloride salts. For example, sodium bicarbonate would have worked just as well as disclosed by Bajpal (see col. 2, see Materials and Methods). Further, sodium bicarbonate is also disclosed in applicant's specification on page 10, line 15, as an optional source of non-chloride salt to form small aggregates of algae cells. Although it is noted that applicant further discloses that fermentation of the claimed strains in the presence of a non-chloride containing sodium salt, particularly sodium sulfate, is optimal. However, optimization of these types of cultures in ferments is well recognized in the art as taught by Bajpal.

The instant claims are deemed *prima facie* obvious.

Claims 14-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Bajpal et al. in view of World Patent 89/00606.

The claims and the cited references are discussed above.

The claimed subject matter differs from the disclosure of Bajpal in that *Schizochytrium* is not specifically taught in this cited reference. It would have been obvious to one of ordinary skill in art at the time of applicant's invention to culture both *Thraustochytrium* and *Schizochytrium* and mixtures thereof to obtain a biomass having high fatty acid content. The provision

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of small aggregates in the biomass would have been desirable to one of skill since the fatty acid content of these culture types are taught to be light dependent. Furthermore, one of skill would have been motivated to obtain a biomass having small cellular aggregates for the reasons discussed above.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245.

DKW.
Deborah K. Ware
October 31, 1994

Marian Knodt

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